REMARKS

Claims 1-15 are presently pending in the application. Claims 5 and 7 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite, with claim 5 identified as an incomplete sentence and claim 7 identified as unclear. Claims 1 and 4-6 stand rejected under 35 U.S.C. §102(b) as anticipated by European Patent Publication No. 0 405 284 A2 to Greiner ("Greiner"), while claims 3, 7, 9 and 11 stand rejected under 35 U.S.C. § 103(a) as unpatentable over this reference. Claim 10 stands rejected under §103(a) as unpatentable over Greiner in view of U.S. Patent No. 6,153,252 to Hossainy, *et al.* ("Hossainy"). Finally, claims 2, 8 and 11-15 stand rejected under §103(a) as unpatentable over Greiner in view of U.S. Patent No. 5,916,585 to Cook, *et al.* ("Cook").

The Applicant has carefully reviewed the October 3, 2002 Office Action, and respectfully submits the foregoing amendments and following remarks in response thereto. Independent claims 1 and 12 have been amended to more clearly recite the present invention, specifically to recite that the medical device is made from a non-polymeric (*i.e.*, non-swelling) material. Claim 5 has been amended to delete the last word in the claim, which was inadvertent typographic error. The Applicant respectfully submits that claim 7 is sufficiently definite in its present form for the reasons set forth below, and therefore respectfully declines the invitation to amend this claim at this time.

In view of the foregoing amendments and following remarks, the Applicant believes claims 1-15 are patentable over the cited references. Accordingly, the Applicant respectfully requests the pending rejections be reconsidered and withdrawn, and claims 1-15 be allowed.

1. The § 112, Second Paragraph, Rejections.

The Applicant has amended claim 5 to delete the extraneous word "upon" at the end of the sentence.

As to claim 7, the Applicant respectfully traverses the §112, second paragraph rejection on the grounds that claim 7, as presently formed, is sufficiently definite. Claim 7 is based on claim 1, and further recites the step of "applying a vacuum force to a chamber containing the medical device." The Applicant respectfully submits that this claim language is sufficiently clear under §112, and is consistent with the description of the invention in the specification.

At Application page 7, the specification states that recycling chamber 31 "may not only be used to draw unused supercritical fluid from the coating chamber 32 it may also be used to increase the rate in which the supercritical fluid *enters* the chamber 32 by placing a

vacuum force in the coating chamber 32 as the supercritical fluid enters the chamber 32." Application at 7:26-8:1. The specification then continues to discuss how the vacuum force should be applied, noting that the pressure in the various tanks should be adjusted to compensate for the vacuum to ensure the supercritical fluid does not drop in pressure and temperature below the supercritical range. *Id.* at 8:1-8. Read in context, the reader of claim 7 is clearly informed that the application of the vacuum force should be done in a manner that ensures that the fluid remains in the supercritical region, thus eliminating the Examiner's stated concern that the claim is unclear as potentially suggesting application of a vacuum in a manner that would render the fluid sub-critical. Accordingly, the Applicant respectfully submits that claim 7, read in context of the specification, sufficiently points out and distinctly claims the invention.

The Applicant respectfully requests reconsideration and withdrawal of the pending §112, second paragraph rejections of claims 5 and 7.

2. <u>Independent Claim 1 Is Patentable Over Greiner</u>.

The Applicant respectfully traverses the § 102(b) rejection of claims 1 and 4-6 as anticipated by Greiner, and the §103(a) rejection of claims 3, 7, 9 and 11 as unpatentable over Greiner, on the grounds that this reference does disclose or suggest the invention recited in independent claim 1, as amended.

The present invention is directed toward a method for coating a medical device such as a stent with a therapeutic material by exposing the medical device to a supercritical solvent into which the therapeutic has been dissolved. Claim 1 has been amended to clarify that this supercritical solution deposition method provides a coating with the desired adhesion and pharmaceutical loading properties on a non-polymeric medical device, *i.e.*, a material that does not swell when exposed to solvents, something not previously taught or suggested in the art.

Greiner is cited as teaching the present invention. October 3, 2002 Office Action at 3. However, review of Greiner reveals that unlike the present invention, Greiner teaches that in order it utilize his method, there is the need to first create a rough, porous surface on the *plastic* ("polymeric") catheter by exposing the catheter to a solvent or swelling agent, and then "impregnating" the swollen surface of the catheter with a material such as an antibiotic. Greiner at 1:3-7 ("impregnating a pharmaceutical *into* a [polymer] catheter by contacting the catheter with a volatile solvent or swelling agent"); 1:52-2:8 ("impregnating a catheter, *made of a polymeric material*, ..."). Moreover, Greiner's description of his invention is focussed

solely on impregnating a swollen plastic (polymeric) device. Nothing in this reference either teaches or suggests that its solution (a pharmaceutical in a supercritical solvent) could be successfully employed to form an acceptable coating *on* a *non-porous* surface such as the smooth metal surface of a stent. Indeed, in Greiner's description, he identifies a number of known methods of creating a catheter with a pharmaceutical, none of which would suggest to one of ordinary skill in the art that he or she should use Greiner's approach with non-swelling medical devices. *See, e.g.,* Greiner at 1:41-51 (listing six different known methods for applying pharmaceuticals to a catheter, none of which suggest a satisfactory coating might be achieved with supercritical solution deposition on non-porous surfaces such as smooth metal stents). Thus, Greiner fails to disclose the present invention as recited in amended claim 1 under §102(b), and further fails to suggest the recited invention under § 103(a).

In view of the above remarks, the Applicant respectfully maintains that Greiner does not anticipate or render unpatentable the present invention, as recited in amended claim 1 or its dependent claims 3-7, 9 and 11. Reconsideration and withdrawal of the pending § 102(b) and § 103(a) rejections is respectfully requested.

3. <u>The Remaining Claims Are Patentable Over the Cited References</u>.

The Applicant respectfully traverses the § 103(a) rejections of claim 10 and claims 2, 8 and 12-15 as unpatentable over Greiner in view of Hossainy and Greiner in view of Cook, respectively, on the grounds that these references do not cure the deficiencies of Greiner.

As noted in the preceding section, Greiner does not disclose or suggest all the features of the present invention recited in amended claim 1, from which claim 10 depends. Hossainy is cited as teaching the use of paclitaxel in implantable medical device coatings. While this specific pharmaceutical is mentioned in Hossainy, this reference does not teach or suggest its combination with Greiner to obtain the present invention, or otherwise suggest any other aspect of the present method. Instead, Hossainy teaches immersion of a medical device in a film-forming bio-compatible polymer. There is no teaching or suggestion in this reference that its method of coating application be combined with Greiner's swelling-and-impregnating method to coat non-polymeric devices in the manner of the present invention. Hossainy thus does not cure the deficiencies of Greiner, and the combination of these references does not render dependent claim 10 unpatentable.

Similarly, Cook also fails to cure Greiner's deficiencies. Cook is cited as teaching the coating medical devices with a hydrophilic polymer layer, followed with a bioactive layer. In fact, Cook states that it "is directed to hydrophobic biodegradable *polymeric* materials ...

rendered more hydrophilic by attachment ... of a hydrophilic layer ..." Cook Abstract. Thus, like Hossainy, Cook relies on the material properties of the plastic device -- specifically, the chemical reaction of the surface layer of the biodegradable polymer medical device with the applied hydrophilic layer -- for the attachment of its coating. Cook Abstract (specifically noting that the hydrophilic layer "is cross-linked together on the surface of the [polymeric] material with a cross-linking agent or scheme ..."). The mere fact that Cook applies a coating to a medical device provides no suggestion that its approach to coating a biodegradable polymeric medical device (chemical interaction of the biodegradable device's surface with the coating material) be combined with Greiner's swollen polymeric device impregnating technique to obtain the present invention's supercritical solution deposition method for non-polymeric devices.

Because Cook does not cure the deficiencies of Greiner noted in the preceding section, the combination of Greiner and Cook also fails to render the claims which incorporating the limitations of amended claim 1 (claims 2, 8 and 12-15) unpatentable under §103(a).

Reconsideration and withdrawal of the pending § 103(a) rejections of claim 10 and claims 2, 8 and 12-15 is respectfully requested.

CONCLUSION

In view of the foregoing remarks, it is respectfully submitted that the presently pending claims are in allowable form. The Applicant therefore earnestly solicits an early and favorable action on the merits and issuance of a Notice of Allowance for claims 1-15.

The Examiner is invited to contact the undersigned at (202) 220-4232 to discuss any matter concerning this application.

The Office is hereby authorized to charge the fee of $110.00 for a Petition for Extension of Time Under 37 C.F.R. § 1.136(a) and any additional fees under 37 C.F.R. § 1.16 or § 1.17 or credit any overpayment to Deposit Account No. 11-0600.

Respectfully submitted,

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MARKED-UP VERSION OF AMENDMENTS

IN THE CLAIMS:

1. (Once amended) A method of coating a non-polymeric medical device comprising:

interfacing a therapeutic with a supercritical fluid; and

transferring the therapeutic from the supercritical fluid to the medical device.

5. (Once amended) The method of claim 1 wherein the therapeutic substantially dissolves in the supercritical fluid [upon].

12. (Once amended) A method of coating a non-polymeric medical device comprising:

placing the [a] medical device in a coating chamber;

coating the medical device;

interfacing a therapeutic with a supercritical fluid; and

exposing the coating to the supercritical fluid.